K011713

JUL - 5 2001

May 31, 2001

[1] 510(k) Summary of Safety and Effectiveness Information

[2] Kimberly-Clark Corporation
1400 Holcomb Bridge Road
Roswell, GA 30076

Telephone: 770-587-8000
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Contact: Marcia Johnson
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[3] Trade Name: "Safeskin Neon Nitrile" – Powder Free Neon Nitrile Exam Glove
Common Name: Patient Examination Gloves
Classification Name: Patient Examination Gloves

[4] The predicate device is a Class I, poly-coated purple nitrile examination glove 80 LZA that meets all of the requirements of ASTM D 3578-00, Standard Specification for Rubber Examination Gloves for Medical Application (with the exception of elongation).

[5] The powder free neon nitrile exam glove will meet all of the requirements of ASTM D 3578-00, Standard Specification for Rubber Examination Gloves for Medical Application (with the exception of elongation).

[6] The powder free neon nitrile exam glove is a medical glove intended to be worn on the hands of healthcare and similar personnel to prevent contamination between such personnel and the patient.

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[7] The powder free neon nitrile exam glove possesses the following technological characteristics (as compared to ASTM or equivalent standards):

| Characteristics | Standards |
|---|---|
| Dimensions | Meets ASTM D 3578-00 |
| Physical Properties (except % elongation) | Meets ASTM D 3578-00 |
| Freedom from pinholes | Meets ASTM D 3578-00<br>Meets ASTM D 5151-99 |
| Powder Free | Meets ASTM D 6124-00<br>Meets ASTM D 3578-00 |

Biocompatability

| | |
|---|---|
| Primary Skin Irritation in Rabbits | Passes |
| Guinea Pig Sensitization | Passes |

[8] The performance test data that support a determination of substantial equivalence are described above.

[9] Clinical data are not needed for examination gloves.

[10] It can be concluded that the powder free neon nitrile exam glove will perform according to the glove performance standards referenced in Section 7 above and therefore will meet FDA requirements and the labeling claims for the product. In addition, this device is substantially equivalent to currently marketed devices.



Kimberly-Clark Corporation 1400 Holcomb Bridge Road Roswell, Georgia 30076-2199 (770) 587-8000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Marcia Johnson
Senior Regulatory Associate
Kimberely-Clark Corporation
1400 Holcomb Bridge Road
Boswell, Georgia 30076

Re: K011713
Trade/Device Name: Safeskin Neon Nitrile- Powder Free Neon Examination Gloves
Regulation Number: 880.6250
Regulatory Class: I
Product Code: LZA
Dated: May 31, 2001
Received: June 4, 2001

Dear Ms. Johnson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**INDICATIONS FOR USE**

Applicant: Kimberly-Clark Corporation

510(k) Number: K011713

Device Names: Powder Free Neon Nitrile Exam Glove

Indications for Use:

A medical glove intended to be worn on the hands of healthcare and similar personnel to prevent contamination between such personnel and the patient.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Over-The-Counter _____

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011713